PSJ3

Exhibit 398

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Slide 1

Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances

Friday, November 14, 2008
1:00 – 2:30 PM (ET)

Question and Answer Period

Please type your questions into the **QUESTIONS** box located on the lower left-hand side of the screen.

Click the **SEND** button when you are ready to submit your question.

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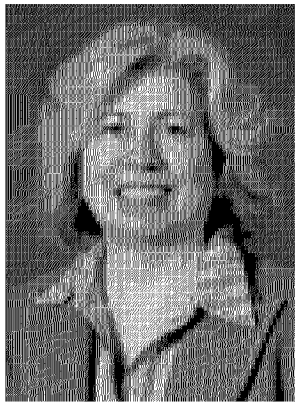
Webinar Overview



Anita T. Ducca
Senior Director, Regulatory Affairs
HDMA

Objectives

- Why HDMA and Members prepared the *Industry Compliance Guidelines* (ICG)
- Discuss DEA's concerns & points for distributors
- DEA actions
- HDMA interaction with DEA
- Legal authority
- "Walk through" the *Industry Compliance Guidelines* & DEA's reaction
- Q & A

Poll Question #1

Would those who are listening in please indicate your key responsibility within your company?

A. Sales/Trade Representative
B. Customer Service/Relations
C. Operations/Warehouse staff
D. Regulatory/Compliance
E. Government Relations
F. Other

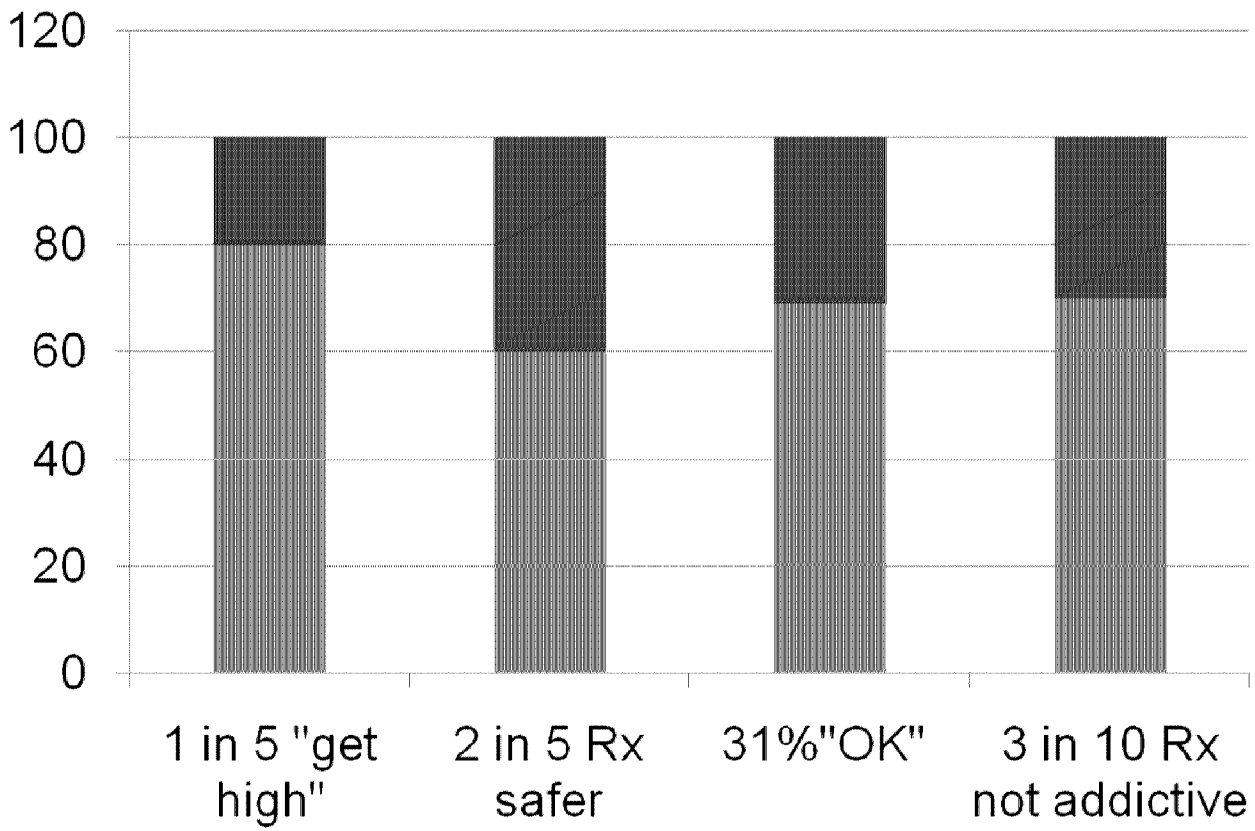
History/Background

- Over last 2+ yrs –
  - DEA meetings with distributors
  - Discuss DEA expectations
- Apparent change in these expectations, e.g., traditional "reporting" no longer adequate
- Intensity stepped up
  - 3 DEA letters
  - Suspended distributor registrations

What is Driving DEA: Rx Drug Abuse

- Increase in prescribing for pain, e.g., between 1999 and 2002
  - Oxycodone Rx ↑ 50%
  - Morphine Rx ↑ 60%
- Non-medical Rx drug abuse ↑~ 80 % from 2000 (3.8 million); 2nd only to marijuana abuse
- Ease of Internet purchasing

Teens' Views on Rx Drug Abuse



SOURCE: 2005 Partnership Attitude and Tracking Study (PATS)
Released April 2006

Joseph Rannazzisi

Deputy Assistant Administrator, DEA

Congressional Testimony - 5/16/07

DEA began an **Internet Distributor Initiative**

… because…

the seller has a **legal obligation** to ensure the substances transferred are **not destined for diversion**...

DEA's educational presentation … is designed to emphasize to wholesalers their obligation **not** to sell where diversion appears to be occurring **or** face the **loss of their DEA registration** or judicial sanctions.

(emphasis supplied)

DEA Points for Wholesale Distributors

- Registrant *cannot* rely on customer's DEA registration and state licensure
- DEA *cannot* tell a distributor if order is legitimate
- *Distributor* must
  - decide which orders are suspicious
  - make a sales/shipment decision
- Distributors selling CSs being dispensed outside the course of professional practice must stop immediately

Concerns About the DEA Distributor Meetings and Guidance

- Guidance was:
  - Ambiguous
  - Inconsistent, e.g., DEA HQ and field staff
  - Inappropriate for distributors
- Unable to rely on DEA registration/state licensure
- Changing emphasis on distributor responsibility:
  - "know your customer"
  - identify, stop shipment and report "suspicious orders"

Enhanced Communications Between HDMA and DEA

To support our members, HDMA worked to:

- Initiated development of an "Industry Compliance Guideline" with our members
- Established a dialogue with the DEA's Chief Counsel's Office & Office of Diversion Control

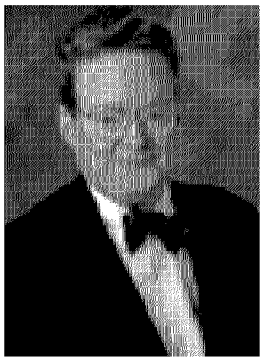
Purpose of ICG and DEA Communications

- Demonstrate our members' commitment
- Distributors part of the solution
- Address urgent needs:
  - Clarify DEA expectations
  - "Educate" DEA
  - Gain consistency in DEA guidance
- "Head-off" further enforcement or regulatory action

Considerations in Developing the ICG

- Must be “robust and adaptable”
- Robust:
  - Rigorous enough to reliably help identify potential problem areas
  - Address DEA compliance expectations
- Adaptable:
  - Can change as criminals modify diversion practices
  - Differing distributor business models
  - Can change with DEA regulatory changes

Presentation by:



David L. Durkin, Esq.
Principal
Olsson Frank Weeda
Terman Bode Matz PC

Preface

- This presentation is for general informational purposes only. It is not intended to and does not constitute legal advice. Please contact your attorneys if you need legal advice.

- The views expressed in this presentation do not necessarily reflect the views of HDMA, its members, or any particular client of OFW.

Industry Compliance Guidelines: Reporting Suspicious Orders And Preventing Diversion Of Controlled Substances

- Rationale for Industry Compliance Guidelines (ICG)
- ICG Structure and Implementation
- DEA Interaction and Moving Forward

Poll Question #2

What does the DEA expect from Distributors with regard to Suspicious Orders? (check all that apply)

A. Monthly reports of excessive purchases

B. A report for each order that is an unusual size or otherwise deviates substantially from the customer's normal pattern

C. Only fill orders of customers when you know who the customer's customers are

D. Stop the entire order for the specific drug code product if it may meet the SO criteria

E. Stop a customer's order for all CS products if any one part of the order is unusual

F. The sun, the moon and the stars

G. All of the above

Statutory Framework: Conditions of Registration

- CSA section 303: Registration permitted if consistent with the "public interest" and international agreements
- First factor in determining the "public interest": "maintenance of effective controls against diversion . . . into other than legitimate . . . channels"

Regulatory Implementation

CSA section 301

- DEA may promulgate and enforce any rules, regulations or procedures relating to registration and control of manufacture or distribution of controlled substances

21 CFR § 1301.74(b)

- Design and operate a system to *disclose* to the registrant suspicious orders of controlled substances
- Inform the local DEA office "when discovered"
- "Suspicious orders include orders of *unusual* size, deviating substantially from a *normal pattern*, and orders of *unusual* frequency."

Security Requirements

- "All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. 1301.71(a)

- "In evaluating the overall security system of a registrant or applicant, the Administrator may consider . . . The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations" *Id.* at 1301.71(b)(14)

"Suspicious Order" Criteria: Anecdotal Advice from DEA

- Quantities of drugs purchased
- % of controlled versus noncontrolled
- Size of orders
- Location of customer
- Only current drugs of concern
- No established business credit
- Frequent large orders

Poll Question #3

"Controlling diversion" means:

A. Ensuring there is no theft, loss, or shrink from your distribution facility;

B. Ensuring that pharmacies, doctors, and clinics do not dispense to persons who will use the CS for illicit purposes; or

C. Both

What Has Changed? September 27, 2006 Letter

- Reporting a suspicious order does not relieve the distributor of the responsibility to maintain effective controls against diversion
- Registrant *cannot* rely on customer's DEA registration and state licensure
- Apparent emphasis on "internet pharmacies"

What Has Changed? December 27, 2007 Letter

- Deviation from "normal pattern" is not only determined by order size
- "Suspicious" nature of order depends not on pattern of ordering customer, but on patterns of registrant's *customer's base* and patterns "throughout . . . the regulated industry."
- "Rigid formulas" may be insufficient

December 27, 2007 Letter (con't)

- "Registrants must conduct an independent analysis of suspicious orders prior to completing a sale"
- "Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, *or should have known*, that the controlled substance were being diverted." (emphasis supplied)

ICG Development

- HDMA Regulatory Affairs Committee
- Reviewed by counsel
- Outreach to related interest groups
- Executive Committee approval
- Presentation to DEA April 15, 2008
- Follow-up DEA Meeting June 4, 2008
- Final DEA Meeting September 5, 2008
- DEA commendation letter – October 23, 2008

Meetings with DEA

- Chief Counsel's Office
- Senior Office of Diversion Control officials
- Purpose:
  - Demonstrate industry commitment,
  - Clarify requirements for distributors, and
  - Seek DEA "Imprimatur"

Guidance Should . . .

- Address DEA Expectations to:
  - "Know your customer"
  - Maintain a "system"
  - Stop shipments (while being examined)
- Reduce HDMA members' compliance risk
- Identify orders that are truly of concern (minimize "false alarms")

ICG At-a-Glance

Introduction

- Distributors' role; purpose of the ICG
- History and general legal requirements
- Distributor's commitment to preventing diversion

ICG At-a-Glance

I. Know Your Customer Due Diligence

- Information Gathering & Review
  - types of Rx & prescribers,
  - % of CS,
  - Internet business activities,
  - prior DEA/state audits
- Independent Investigation
- Confirmation with local DEA office, state BOP
- Internet search

ICG At-a-Glance

II. Monitoring for SO's

- System design
  - Electronic system; written SOPs; assign responsibilities

- Identify Product & Customer Characteristics
  - establish groups or "families" of drugs based on class of trade &/or product
  - Contact with DEA field offices and nationwide sources to be alert to changing "Drugs of Concern" http://www.deadiversion.usdoj.gov/drugs_concern/index.html

ICG At-a-Glance

II. Monitoring for SO's *Change the Language*

- "Orders of Interest" vs. "Suspicious Orders"
- Examine possibility of mistake
- Prevent over-reporting
- Provide more meaningful reporting to DEA

ICG At-a-Glance

II. Monitoring for SO's

- Develop "Thresholds" To Identify "Orders of Interest"
  - Calculate "average" orders for "families"
  - Identify orders of "unusual" size/frequency/pattern
  - Cumulative orders

- Other circumstances that warrant follow-up inquiry to determine if "suspicious"
  - New information on drugs of concern
  - Recent DEA enforcement activity

ICG At-a-Glance

III. Suspend/Stop An Order Of Interest

If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor ***should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest***.

ICG At-a-Glance

IV. Investigation of Orders of Interest

- Initial Review – Why did it trigger a threshold? Error? Change in customer business?
- Investigate the Order – If initial review inconclusive, perform a more intensive review, e.g., prior orders, interview customer, verify customer input
- Seek additional information

ICG At-a-Glance

IV. Investigation of Orders of Interest (Con't)

- Documentation -- Names, titles, dates, other; keep copies of written information
- Flexible SOPs
- Evaluate future customer orders/relations in light of reportable "suspicious order"
- Assumes order is on hold while under review

ICG At-a-Glance

V. File Suspicious Order Report

- Immediately report to DEA by phone – (see 21 CFR § 1301.74(b))
- Report even if all circumstances unclear, e.g., not yet a customer, but gives information on intentions
- Timeliness crucial
- Written follow-up strongly recommended
- Documentation

ICG At-a-Glance

VI. Employees, Training & SOPs

- Review DEA regulations; cover firm's compliance steps
- Expand staff training, e.g., operations, customer service and sales, those filling orders
- SOP review and revision minder

ICG At-a-Glance

VII. Additional Recommendations

- Periodic audits
- Review/revise SOPs, monitoring systems, training
- Update customer records

DEA Reaction

- Initially - Only one question: Please clarify “what is stopped [when a threshold is exceeded]?”
- Acknowledgement that DEA retains full enforcement discretion
- Overall, very favorable reaction

Additional Points

- The ICG is ***not*** an industry standard
- HDMA will not “enforce” the ICG
- DEA will “enforce” -- even if following the ICG
- Distributors are ***not*** deputized criminal investigators

Poll Question #4A – 2 Questions

A) Has your company either revised their Suspicious Order Monitoring systems and SOPs or initiated substantial efforts to revise them within the past year?

A) Yes
B) No
C) Don't know

Poll Question #4B

B) If "Yes" to the previous question, have you used the ICG to help develop your revisions?

A) Yes
B) No
C) Don't know

What Does the ICG Mean for Me?

- Robust procedures will have two positive effects:
  - Actual decrease in diversion
  - Defensible position in the event of investigation

Wrap-Up

- HDMA fully recognizes that much is expected
- Based on DEA input
- DEA's concerns continue - enhanced regulatory climate likely
- Prepared by making strong headway in constructive dialogue with agency

Question and Answer Period

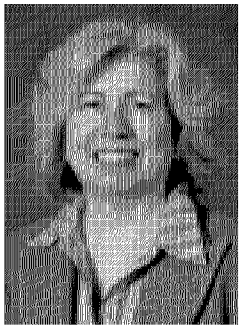
Please type your questions into the **QUESTIONS** box located on the lower left-hand side of the screen.

Click the **SEND** button when you are ready to submit your question.

Conclusion

- Thank you for your participation!
- Site coordinators – please fax back the “List of Participants” to HDMA at (703) 935-3200
- Please complete the on-line webinar evaluation

Speaker Contact Information



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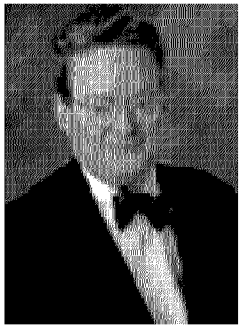

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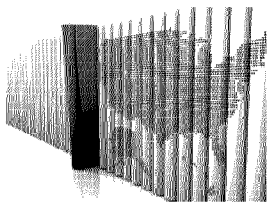
HDMA Marketplace

Newly Released!

2008-2009 HDMA Factbook

Gain up-to-the-minute healthcare marketplace and supply chain trends; analyses; easy-to-use demographic and benchmarking data; and the focused facts you need to improve your business strategies, processes and efficiencies.



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